UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

SARA ALI and DANIEL ALI, Plaintiffs, v. ALLERGAN USA, INC., Defendant.	)	Case No.: 1:12-cv-00115-GBL-TRJ

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS AMENDED COMPLAINT

Pursuant to Federal Rules of Civil Procedure 9(b), 12(b)(6) and 12(e), Defendant Allergan USA, Inc. ("Allergan") files this Memorandum in Support of Motion to Dismiss Amended Complaint to show the Court as follows:

PRELIMINARY STATEMENT

The LAP-BAND® Adjustable Gastric Banding System ("LAP-BAND®") is an FDA-approved medical device used by doctors to induce weight loss in severely obese patients. Plaintiffs assert a variety of state-law causes of action and seek personal injury damages from Allergan with respect to a LAP-BAND® that was implanted into Plaintiff Sara Ali.

Federal law preempts each of Plaintiffs' claims. The LAP-BAND® has been approved by the federal Food and Drug Administration ("FDA") as a Class III device under its rigorous Premarket approval ("PMA") process. The FDA has thoroughly and repeatedly analyzed and approved the design, manufacturing process, and labeling for this medical product. Plaintiffs' claims seek to impose state law standards that are different from or in addition to those imposed upon Allergan by federal law and are thus preempted under the express preemption provision of

the Medical Device Amendments ("MDA")[1] to the Federal Food, Drug & Cosmetic Act ("FDCA").[2] The U.S. Supreme Court in *Riegel v. Medtronic, Inc.*,[3] has definitively decreed that such claims are expressly preempted. The FDA's premarket approval of the LAP-BAND® is a matter of public record, and its decision is the final word on preemption. Accordingly, the Court can decide this issue on the basis of the FDA documents described below, and no discovery or case-specific fact development is necessary or appropriate.

Independently, Plaintiffs have failed to state a claim for fraud with particularity. Representations that the product was "safe and effective" are consistent with the FDA-approved labeling, and the statements about relative risks are true and correct. Plaintiffs' conclusory allegations that Allergan's advertising was "deceptive" and that the company "made false representations" fall far short of the requirement of Federal Rule of Civil Procedure 9(b) that such claims be pled with particularity. Their allegation in the Amended Complaint that these misrepresentations can be found in "information distributed to the public, including Plaintiff, the medical and health-care community, and the FDA, by the defendant includ[ing], but [] not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial medical [sic] containing material representations,"[4] proves Allergan's point. Nowhere in the Amended Complaint do Plaintiffs specify any particular statement, oral or written, that puts Allergan on notice of any misrepresentation relevant to the claimed injuries.

[1] 21 U.S.C. § 360k.

[2] 21 U.S.C. § 301 *et seq.*

[3] 552 U.S. 312 (2008).

[4] Amended Complaint (Docket #31) ¶ 45.

The fraudulent concealment claims are likewise deficient. The allegations in that regard—*e.g.*, that Allergan failed to disclose potential malfunctions and side effects—are mere recasts of a failure to warn claim, which is entirely preempted. Nor do Plaintiffs give sufficient detail as to what information should have been conveyed, to whom, and in what medium. As a result, these claims should be dismissed.

Plaintiffs add breach of express and implied warranty in their Amended Complaint, but these claims too fail to escape preemption. The "express warranties" that Plaintiffs globally allege—that the LAP-BAND® "was safe and effective," "fit for use by consumers, fit and proper for its intended use, and that it was of merchantable quality"[5]—are the same types of statements covered by the FDA-prescribed LAP-BAND® labeling and other aspects of the PMA process and so are preempted. Plaintiffs do not allege any voluntary warranties made by Allergan outside of the labeling, and the remaining allegations merely mirror their otherwise preempted state-law claims. In fact, Allergan has expressly disclaimed any such warranties.

The newly added claims for violations of the Virginia consumer protection and false advertising statutes fare no better. They are also preempted and are fatally defective in other independent respects, including Plaintiffs' failure to state any basis for violations with the requisite specificity. For any and all of these reasons, Plaintiffs' Amended Complaint should be dismissed in its entirety.

[5] Amended Complaint ¶ 84. Plaintiffs appear to confuse implied and express warranties in this allegation.

FACTUAL BACKGROUND[6]

A. Class III Medical Devices Approved Through the PMA Process Are Strictly Regulated

The LAP-BAND® is a Class III device that was approved by FDA under its premarket approval process. *See* Ltr. from Daniel G. Schultz, M.D. of FDA's Center for Devices and Radiological Health to Ellen Duke of BioEnterics dtd. 6/5/01 (Exhibit A).[7] Premarket approval is a "rigorous" process in which "FDA spends an average of 1,200 hours reviewing each application." *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008). Only a small number of devices receive PMA—FDA approved twenty-six devices in 2008, twenty devices in 2009, and twenty-seven in 2010. *See* FDA, Recently Approved Devices, http://www.fda.gov/MedicalDevices/

[6] For purposes of Allergan's Motion to Dismiss, the allegations of Plaintiffs' Amended Complaint are taken as true. However, Allergan in no way agrees that these allegations are factually correct and will demonstrate otherwise at the appropriate time.

[7] This document is available on the FDA's official website at *http://www.accessdata.fda.gov/cdrh_docs/pdf/P000008a.pdf* (last visited Feb. 14, 2012). It is attached as Exhibit A to *Allergan's Renewed Motion to Take Judicial Notice in Support of Motion to Dismiss Amended Complaint* ("Motion to Take Judicial Notice"), filed contemporaneously. In considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a court may consider certain materials that are outside the pleadings, such as "matters of which a court may take judicial notice." *See, e.g., Tellabs v. Makor Issues & Rights*, 551 U.S. 308, 322 (2007) (citing 5B WRIGHT & MILLER § 1357 (3d ed. 2004 & Supp. 2007)); *Philips v. Pitt Cnty. Mem. Hosp.*, 572 F.3d 176, 180 (4th Cir. 2009); *Bailey v. Black Entm't TV, Inc.*, No. 3:09CV787, 2010 U.S. Dist. LEXIS 43190, at *8 (E.D. Va. May 3, 2010); *see also Hall v. Virginia*, 385 F.3d 421, 424 n.3 (4th Cir. 2004). Documents maintained by FDA on its official website are the kinds of materials that are appropriate for such consideration. *See Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (holding that trial court properly took judicial notice of "publicly-available documents and transcripts produced by the FDA" relevant to premarket approval of the device at issue); *see also Bayer Schera Pharma AG v. Sandoz, Inc.*, 741 F. Supp. 2d 541, 545 & n.4 (S.D.N.Y. 2010) (considering publicly available documents submitted to FDA in Rule 12(b)(6) dismissal because they were integral to the issues before the court).

ProductsandMedicalPRocedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/default.htm (last visited Feb. 14, 2012) (Exhibit B).[8]

As part of the PMA application, a manufacturer must submit what is typically a multi-volume application including, among other things:

- "full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant";
- "a 'full statement' of the device's 'components, ingredients, and properties and of the principle or principles of operation'";
- 'a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device';
- "samples or device components required by the FDA"; and
- "a specimen of the proposed labeling."

Riegel, 552 U.S. at 318 (citing 21 U.S.C. § 360e(c)(l)). "Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, and may request additional data from the manufacturer." *Riegel*, 552 U.S. at 318 (citations omitted).

FDA "weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* (citing 21 U.S.C. § 360c(a)(2)(C)). FDA "may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Id.* As part of the PMA process, FDA also must review a device's proposed labeling and determine that it is neither "false nor misleading." *Id.* (citing 21 U.S.C. § 360e(d)(l)(A)). FDA only grants PMA if it finds there is "reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. § 360e(d).

[8] *See* note 7, *supra*. All exhibits referenced in the text are attached to Allergan's Motion to Take Judicial Notice.

B. The LAP-BAND® Received FDA Approval Through the Rigorous PMA Process

The LAP-BAND® has been in use in Europe since 1993, and regulatory approval was obtained for the device in Australia (1994), Canada (1998), Israel (1997), Mexico (1996), and other countries. *See* FDA, *The LAP-BAND® Adjustable Gastric Banding System Summary of Safety and Effectiveness Data* at 9 ("Marketing History") (Exhibit C).[9] At the time the LAP-BAND® was approved for distribution in the United States, over 50,000 LAP-BAND® Systems had been distributed internationally, and according to FDA, the product had been "widely reported on in the medical literature." *Id.*

Allergan's predecessor, BioEnterics, submitted an Investigational Device Exemption ("IDE") to FDA in order to conduct a clinical study to assess the safety and effectiveness of the LAP-BAND® in the United States. Exhibit C at pp. 12-24 ("Summary of Clinical Studies"). The clinical trials were conducted at eight clinical sites involving almost 300 patients beginning in April 1995 and continuing periodic evaluations of these patients over a 36-month interval. *Id.* at p. 12.

The initial PMA application consisted of several volumes of submissions and included the results from the first two years of the clinical trial on the safety and effectiveness of the LAP-BAND®. *See* Exhibit C at 10-23. As required by federal law, the PMA included detailed reports of both pre-clinical and clinical studies, including component mechanical testing for all components, biocompatibility testing, and packaging and sterilization testing. *See* Exhibit C at pp. 10-11; *see also* 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20(b)(3), (4), (6), (8), (9) & (10)

[9] This publication is available at http://www.accessdata.fda.gov/cdrh_docs/pdf/P000008b.pdf (last visited Feb. 14, 2012).

(1999). It also contained comprehensive analysis of the clinical trials of the product. Exhibit C at pp. 12-23.

In connection with the submission of the PMA for the LAP-BAND®, BioEnterics also submitted the specific proposed wording and content for labels for the LAP-BAND®. 21 C.F.R. §§ 801.5, 814.20(10) (1999). The LAP-BAND® labeling contained a detailed description of the product, the purposes for which it is intended, and directions for its use, as well as its contraindications, warnings, precautions, and adverse reactions, *e.g.*, 21 C.F.R. § 801.5—as the FDA evaluates safety and effectiveness under the conditions of use set forth on the label. *See* 21 U.S.C. § 360c(a)(2)(B).

Additionally as part of the PMA process, BioEnterics submitted to FDA, and FDA approved, an informational booklet for patients called "A Surgical Aid in the Treatment of Morbid Obesity: LAP-BAND® Adjustable Gastric Banding System Information for Patients" ("Patient Information") (Exhibit D).[10]

FDA referred the application to its Center for Devices and Radiological Health ("CDRH"), which completed the review of the LAP-BAND® PMA. *See* Exhibit C at p. 24. CDRH consulted with the Gastroenterology and Urology Devices Panel, which met on June 19, 2000, to consider the safety and effectiveness of the LAP-BAND®, and the panel voted (six to four) to recommend that the application be denied and that follow-up data be collected on the patients in the trials for three years. *Id.* On August 7, 2000, FDA sent BioEnterics a deficiency letter that required BioEnterics to provide three years of patient follow-up, as well as making other recommendations concerning the labeling and a post-approval study. *Id.* Accordingly,

[10] A copy of the FDA-approved Patient Information booklet is available on FDA's website at http://www.accessdata.fda.gov/cdrh_docs/pdf/P000008c.pdf (last visited Feb. 14, 2012).

BioEnterics continued its clinical study and amended its PMA application on December 26, 2000, including the additional patient follow-up data. *Id*.

After reviewing the amended submission, CDRH, on behalf of FDA, granted PMA for the LAP-BAND® on June 5, 2001, based on its finding that the LAP-BAND® is safe, effective, and properly labeled. Exhibit A. FDA concluded that "[t]he pre-clinical and clinical data provide reasonable assurance of the safety and effectiveness of the LAP-BAND® System for use in weight reduction for severely obese patients, when the system is used in accordance with its labeling." Exhibit C at p. 23. The approval was subject to a number of conditions ("Conditions of Approval"), including the restriction of sale and distribution of the device to prescription use. *See* Exhibit A at p. 1; *see also* 21 C.F.R. § 801.109 (1999). FDA further restricted the LAP-BAND® to use by trained practitioners in accordance with the requirements of the labeling. *See* Exhibit A at p. 1. FDA also required as a condition of approval that BioEnterics continue with U.S. clinical trials for a total of five years after implantation. *Id*. at 1, 4-5.

C. The LAP-BAND® Continues to be Regulated by FDA

FDA's review of the safety and effectiveness of the LAP-BAND® did not cease when the device was approved. Since the PMA for the LAP-BAND® was issued, the device has been subject to reporting requirements as to new clinical studies, potentially adverse events, and developments in the scientific literature regarding the device. *See* 21 USC § 360i; 21 C.F.R. §§ 803.50(a), 814.84(b)(2) (1999); *see also* Exhibit A at pp. 5-6.

Further, Allergan cannot unilaterally make changes in the design or manufacturing process set forth in the PMA or the labeling as approved by the FDA without FDA approval. 21 U.S.C. § 360e(d)(6)(A)(i); *see also* Exhibit A at p. 3.

D. FDA Recently Reviewed and Approved an Expanded Use for the LAP-BAND®

On April 27, 2010, Allergan submitted a supplement to the LAP-BAND® PMA requesting that the approval be expanded to patients with a body mass index ("BMI") of at least 35 kg/m^2 or a BMI of at least 30 kg/m^2 with an obesity-related co-morbid condition. *See* FDA Executive Summary Memorandum, Gastroenterology and Urology Devices Advisory Panel: LAP-BAND® Adjustable Banding System Allergan (2010) (Exhibit F) at 5.[11] In connection with this submission, Allergan submitted detailed clinical trial and other information supporting the safety and efficacy of the product for this expanded class of patients. On February 16, 2011, FDA approved the PMA supplement. *Id.*; *see also* Exhibit E at p. 1.[12] The approval reiterated the prior restrictions on the product to prescription use by specially trained physicians and continued periodic reports of clinical trial patients in whom the device was implanted. *Id.* at p. 1-2. FDA also obtained Allergan's agreement to conduct two post-approval studies to "evaluate the long-term effectiveness of the device and the incidence of adverse events." *Id.* at pp. 2-3. The approval letter detailed the comprehensive protocol and reporting requirements for these studies. *Id.*

E. Plaintiffs' Claims

Plaintiffs allege that plaintiff Sarah Ali was surgically implanted with a Lap-Band® System on December 17, 2009. Amended Complaint, ¶¶ 18-19. A week later, following difficulty breathing and swallowing, plaintiff Sarah Ali underwent a second bariatric surgery,

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[11] This document is also available on FDA's website at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM235262.pdf (last visited Feb. 14, 2012).

[12] This approval letter is available on the FDA website at: http://www.accessdata.fda.gov/cdrh_docs/pdf/p000008s017a.pdf (last visited Feb. 14, 2012).

during which the original Lap-Band® System was explanted and replaced with another Lap-Band® System. *Id.* ¶ 20. On April 15, 2011, plaintiff Sarah Ali was admitted to the hospital with complaints of severe abdominal pain, and on April 19, 2011 tests revealed that the Lap-Band® System implanted on December 23, 2009 had eroded. *Id.* ¶ 21. On April 20, 2011, plaintiff Sarah Ali underwent a third surgery to remove the Lap-Band® System, during which the doctor performing surgery discovered "a dense extensive inflammatory mass extending from the left upper quadrant to the right lower quadrant surrounding the tubing of the LAP-BAND, phlegmon formation, and multiple abscesses." *Id.* ¶¶ 22-23. Accordingly, Plaintiffs allege that Allergan is liable for their damages including "severe and permanent injuries, including significant abdominal pain, need for emergency open abdominal surgery to remove the eroded LAP-BAND, a dense extensive inflammatory mass extending from the left upper quadrant to the right lower quadrant, surrounding the tubing of the LAP-BAND, phlegmon formation, multiple abscesses, pain and mental anguish, including diminished enjoyment of life" and seek economic and non-economic damages, statutory damages, and attorneys' fees. *Id.* ¶¶ 50, 58, 82, 96, 107, 122, 128.

ARGUMENT AND AUTHORITIES

I. The Court Should Dismiss Plaintiffs' Amended Complaint Because the Claims Have Been Expressly Preempted By Congress in the MDA

The undisputed facts establish that FDA, through the PMA process, approved the LAP-BAND® as safe, effective and properly labeled. For Plaintiffs to prevail on their state-law claims, a jury must second-guess the FDA's decisions on its approved testing, design, manufacturing process, and warnings for the LAP-BAND® and find, in effect, that Allergan should have conformed to safety requirements different or in addition to those imposed by FDA. As confirmed by *Riegel* and subsequent cases, the MDA expressly bars these claims.

A. Express Preemption Bars State Law Claims That Impose Requirements "Different From, or In Addition to" Federal Requirements

The Supreme Court's decision in *Riegel* held that 21 U.S.C. § 360k(a)—the express preemption provision of the MDA—preempts Plaintiffs' claims. First, *Riegel* held that FDA's PMA process for Class III medical devices imposes device-specific federal requirements that have a preemptive effect under the MDA. *Riegel*, 552 U.S. at 332-33. Second, *Riegel* held that federal law preempts state common law claims like the ones Plaintiffs assert here because, if successful, those claims would impose requirements that are "different from, or in addition to" federal requirements. *Id*. at 324-25.

In *Riegel*, the plaintiff sued Medtronic, Inc., after a Medtronic catheter—for which the FDA had granted PMA—burst inside the plaintiff's coronary artery during angioplasty. *Id*. at 320. The plaintiff sued Medtronic under New York common law theories of strict liability and negligence in the design, testing, inspection, distribution, labeling, marketing and sale of the catheter, and breach of implied and express warranties. *Id*. The district court dismissed the plaintiffs' claims because they sought to impose duties on Medtronic that were different from, or in addition to, FDA requirements. *Id*. at 320-21.

The MDA's preemption provision, 21 U.S.C. § 360k(a), provides that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Construing this provision, the Supreme Court held that state law claims are expressly preempted whenever (i) specific federal requirements apply to a particular medical device that is subject to the state law claim, and (ii) the state law claim imposes a standard of

care or behavior that is "different from, or in addition to" the specific federal requirements. *Riegel*, 552 U.S. at 321-25.

As to the first condition, the Supreme Court analyzed FDA's "rigorous" premarket approval process and concluded that PMA imposes "specific federal requirements" applicable to a particular device that have preemptive effect under 21 U.S.C. § 360k(a). *Id*. at 317, 321.

As to the second condition, *Riegel* held that private tort claims are preempted because they have the potential to impose requirements that "are different from, or in addition to" federal requirements. *Id*. at 330. The Court reasoned that private lawsuits based on state law have the same—if not greater—potential to interfere with FDA's regulatory regime as state legislative or agency action:

> State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.

Id. at 325. Accordingly, the Supreme Court in *Riegel* concluded that "reference to a State's 'requirements' includes its common-law duties." *Id*. at 324. Because the state tort claims sought to impose requirements that would be "different from or in addition to" the federal laws governing medical devices, the Court concluded they were preempted. *Id.* at 324-25. 330. Consequently, the Court affirmed dismissal of claims based on strict liability, breach of implied

warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the device. *Id*. at 330.[13]

B. Plaintiffs' State Law Claims Would Impose Requirements "Different From, or in Addition to" Federal Claims and so Are Preempted

The MDA expressly preempts the claims brought by Plaintiffs in this case. Traditional products liability claims for design, manufacturing, and marketing defects, as well as general negligence and breach of implied warranty, attempt to impose state law requirements that are "different from, or in addition to" federal requirements imposed by the PMA process and so are preempted. *See Riegel*, 552 U.S. at 330. Plaintiffs are aware of *Riegel's* application on traditional products claims, and so they instead assert claims for fraud by negligent misrepresentation, fraud by nondisclosure, negligence with respect to violations of FDA requirements, warranty, and violations of Virginia consumer protection and false advertising statutes. In this regard, they appear to be attempting to bypass *Riegel*. On the face of the pleadings, this attempt is wholly unavailing.

1. The fraud and non-disclosure claims are precluded under the MDA

Many of the allegations sound like failure to warn claims dressed up as "misrepresentations." *E.g.*, Amended Complaint ¶ 27 ("Allergan represented . . . that the LAP-BAND had been tested and found to be safe and effective."); *see id.* ¶ 36 ("ALLERGAN's LAP-BAND advertising ***inadequately informed*** Plaintiff SARA ALI ***of potential risks and failed to provide the relevant warnings, precautions, side effects, and contraindications*** related to the

[13] The Supreme Court's recent decision in *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187 (2009), in which the Court held that FDA's approval of ***prescription drug*** labeling does not preempt a plaintiff's state law tort lawsuit, in no way limits or modifies *Riegel's* holding because the FDCA does not contain an express preemption provision like the one in the MDA. In fact, the Supreme Court in *Levine* re-affirmed that ***medical devices*** are subject to the MDA's preemption clause. *See Levine*, 129 S. Ct. at 1196, 1200.

LAP-BAND and the LAP-BAND surgery." (emphasis added)); *id.* ¶ 37 ("ALLERGAN's advertising was and is deceptive and ***fails to disclose the relevant warnings, precautions, side effects and contradictions*** required by the FDA (emphasis added)). Likewise, Plaintiffs' vague claims that the advertising failed to provide "the relevant warnings, precautions, side effects and contraindications," *e.g.*, Amended Complaint ¶ 37, and that Allergan "suppressed and actively concealed" the alleged fact "the LAP-BAND was not safe and effective," that it "would break and/or fail," and that it "would malfunction while it was in use," *id.* ¶ 53, are in fact challenges to the adequacy of the FDA-approved labeling. These claims are clearly preempted.

As noted, FDA specifically approved the warnings contained in the LAP-BAND® Directions for Use. *See* 21 U.S.C. § 360e(d)(l)(A) ("In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling."). Given the express preemption provisions of the MDA, Plaintiffs may not second-guess FDA's approval of that labeling by trying to convince a jury that some additional warning was required. In *Riegel*, the Supreme Court specifically held that "the MDA would pre-empt a jury determination that the FDA-approved labeling for a [medical device] violated a state common-law requirement for additional warnings." *Riegel*, 552 U.S. at 329; *see also Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 286-87 (E.D.N.Y. 2009) (Failure-to-warn claim against a medical device manufacturer was preempted because "[a]llowing the claim to proceed would permit a jury to find that defendants were required to provide warnings above and beyond those on the product label—a label that was specifically

approved by the FDA as part of the PMA process."). Accordingly, as in *Riegel* and *Horowitz*, any claim premised on the theory that Allergan should have provided warnings "different from, or in addition to" those approved by FDA is preempted.

The assertions to the effect that Allergan represented the LAP-BAND® to be "tested" and "safe and effective" are also preempted. FDA has made that determination in approving the LAP-BAND® PMA. *See, e.g.*, Exhibit C at p. 23 ("The pre-clinical and clinical data provides reasonable assurance of the safety and effectiveness of the LAP-BAND® System for use in weight reduction in severely obese patients, when the system is used in accordance with its labeling."). Plaintiffs do not allege—nor can they—that Allergan deviated from the FDA-approved labeling from LAP-BAND® in its packaging or advertising.

In their Amended Complaint, Plaintiffs try to bolster their fraud claims by adding allegations about articles purportedly reporting on "band erosions" and other complications and adverse events. *E.g.*, Amended Complaint ¶¶ 30-34.[14] Even crediting these allegations as true does not salvage Plaintiffs' claims here. The FDA-approved warnings clearly indicated that band erosion—which is alleged by Plaintiffs to have caused Sara Ali's injuries—was a possible complication of the LAP-BAND® surgery and provided specific information to surgeons as to precautions and best practices to prevent erosion. *See, e.g.*, Exhibit C at 3-6, 10. Moreover, these warnings suggest that erosion can result from a variety of causes, including the surgical implantation process and use of anti-inflammatory agents, none of which is attributable to Allergan. Thus, these allegations do not support an inference, much less a conclusion, that the

[14] Plaintiffs' reference to Representative Waxman's request to the U.S. House of Representatives to investigate the "safety and effectiveness" of the LAP-BAND® device, Amended Complaint ¶ 35, is likewise ineffective to support a parallel claim, considering that Plaintiffs do not demonstrate that Rep. Waxman's comments are connected to Sara Ali's claims in any way other than the fact that she claims injury from a LAP-BAND®.

LAP-BAND® devices implanted into Sara Ali were in any way defective or that Allergan's conduct had anything to do with her injuries.

2. Plaintiffs' negligence allegations are not parallel and are thus preempted

a. The "parallel" claim surviving MDA preemption is quite restricted

It is true that *Riegel* left open the possibility that some state law claims would not be preempted—but the category of claims that are not preempted is narrow indeed and is not implicated in this case. As the Supreme Court explained, the MDA "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" because "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330. But it did not have the opportunity to address those so-called "parallel" claims because the plaintiffs in *Riegel* had not argued that possibility to the lower courts. *Id.* As the Eighth Circuit explained:

> *Riegel* and *Buckman*[15] create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).

In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (italics in original)). As the Seventh Circuit aptly noted, *Riegel* "made clear that section 360(k) protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but

[15] In *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348-49 (2001), the Supreme Court held that claims for damages based on alleged fraudulent misrepresentations to the FDA were impliedly preempted.

it does not extend protection from liability when the claim is based on a *violation* of federal law." *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010) (italics in original).

The very limited "parallel claim" that is not foreclosed by *Riegel* would also have to have a causal nexus to a violation of federal regulations or the PMA. For example, in *Burgos*, the court held that the plaintiff could not state a claim for negligence under New York law based on a purported failure by the manufacturer to comply with federal record-keeping requirements because there was no causal nexus between that violation and the injury at issue. *Burgos v. Satiety, Inc.*, No. 10-cv-2680(JG)(RLM), 2011 WL 1327684, at *3 (E.D.N.Y. Apr. 5, 2011). A number of other courts have recognized this causal requirement. *See Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 155 (S.D.N.Y. 2011); *Horowitz*, 613 F. Supp. 2d at 282 (plaintiffs failed to state a viable, parallel claim because they could not show a cognizable link between the defendant's federal violation and the plaintiff's injury).

Further, in order for Plaintiffs to establish a claim based on violations of federal law, they would need findings from FDA to that effect. Under the doctrines of implied preemption, *see Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348-49 (2001), or primary jurisdiction, FDA, as the agency entrusted by Congress to regulate medical devices, is uniquely qualified and empowered to make the often complex decisions about whether its regulations have been violated.

Implied preemption has been applied to bar a claim based on distribution of an allegedly "adulterated" product on the basis that the FDA—which is the only entity that can determine that a particular product was "adulterated"—had made no such finding. *See Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994). As was the case in *Gile*, FDA has not made any findings that Allergan violated its regulations or that its LAP-BAND® device was

adulterated. In fact, the converse is true—FDA in 2010 reapproved LAP-BAND®'s design and labeling in connection with its PMA Supplement.

The doctrine of primary jurisdiction is also designed to defer to FDA's role as the nation's expert on matters of medical devices in general and the LAP-BAND® in particular. *See Far East Conference v. United States*, 342 U.S. 570, 574 (1952) (characterizing primary jurisdiction as the "principle, now firmly established, that in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over"); *see also Gordon v. Church & Dwight Co.*, No. C 09-5585 PJH, 2010 WL 1341184, at *1 (N.D. Cal. Apr. 2, 2010) ("The court finds that the action must be dismissed because the scope and content of condom labels are within the primary jurisdiction of the FDA."); *Aaronson v. Vital Pharms., Inc.*, No. 09–cv–1333, 2010 U.S. Dist. LEXIS 14160, at *7 (S.D. Cal. Feb. 17, 2010) ("[W]hether Redline and/or its ingredients should be approved as safe . . ., these issues are best suited for the FDA."); *see also Bernhardt v. Pfizer, Inc.*, No. 00 Civ. 4042 LMM, 2000 WL 1738645, at *2-3 (S.D.N.Y. Nov. 22, 2000) (deferring to the primary jurisdiction of FDA the decision whether to issue emergency notice pertaining to hypertension product, Cardura, finding that "[t]he FDA, not this Court, has the relevant expertise"). FDA reviewed and approved the PMA for LAP-BAND® in 2001, has required and reviewed reports from Allergan and its predecessors since that time, and has recently expanded its approval of the product. Far from making any findings that would support a parallel claim against Allergan, FDA's 42-page Executive Summary Memorandum prepared in connection with its 2010-11 review of the PMA Supplement makes detailed observations as to the safety and efficacy of the product based on a careful and thorough review of all of the information relating to the device. *See generally* FDA

Executive Summary Memorandum (2010) (Exhibit F). Consequently, Plaintiffs' attempt to state a parallel claim should be rejected.

b. Plaintiffs' allegations of "negligence" fail to state a parallel, non-preempted claim

In their Amended Complaint, although Plaintiffs detail the federal laws that apply to the LAP-BAND®, they never identify which laws in particular Allergan may have violated. *See, e.g.*, Amended Complaint ¶¶ 64-79. Their Amended Complaint essentially assumes that because Sara Ali was injured, Allergan must have violated one or more of the federal laws governing its device operations. Plaintiffs' speculation that Allergan must have violated a wide variety of different federal laws, *see, e.g.*, Amended Complaint ¶¶ 64-67, 70-77, is entirely insufficient to support a parallel claim. A plaintiff cannot avoid preemption through such unspecified accusations. *See Desabio v. Howmedica Osteonics Corp.*, ___ F. Supp. 2d ___, No. 09-CV-287S, 2011 WL 4074391, at *5 (W.D.N.Y. Sept. 13, 2011) (rejecting request for leave to amend where proposed complaint stated only "new allegations of a manufacturing defect resulting from Defendants' violations of unspecified 'general' and 'particular' federal standards"); *see also In re Medtronic, Inc.*, 623 F.3d at 1206 ("Absent concrete allegations that the product sold by Medtronic was not the product design approved in the PMA Supplement, these are not parallel claims."); *Gelber v. Stryker Corp.*, 752 F. Supp. 2d 328, 334 (S.D.N.Y. 2010) ("Plaintiffs cannot simply incant the magic words [Stryker] violated FDA regulations in order to avoid preemption." (internal quotations and citation omitted)); *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at *14 (M.D.N.C. Aug. 5, 2009) ("[T]o survive [a] motion to dismiss, Plaintiffs' complaint must put [the defendant] on notice both of the nature of his claims . . . as well as the grounds upon which he maintains he is ultimately entitled to relief (*i.e.*, the factual basis for the allegations that his injuries were caused by [the defendant's] violation of ***an identifiable federal***

requirement or requirements)" (emphasis added)); *Horowitz*, 613 F. Supp. 2d at 284 ("Without more specific allegations explaining how defendants' manufacturing process was in violation of federal requirements so that the device was defective, plaintiff's claim falls directly within the MDA's preemption provision.").

Here, Plaintiffs' general allegations of conduct violating federal law are themselves qualified—being made "upon information and belief"—which underscores the lack of specific allegations to support a parallel claim.[16] These allegations are worse than the ones rejected by the Western District of New York in *Desabio*, where the plaintiffs claimed that defendants were "not in compliance with the [FDA's] [PMA] standards for Class III devices in general and this device in particular," "had an impurity, imperfection and/or other product defects allowed to be created, contained or placed within the product in the Defendant's manufacturing process," and which "impurity, imperfection and other product defects were a deviation from the Defendants' design and quality manufacturing standards . . . approved by the FDA." 2011 WL 4074391, at *5; *see also Horowitz*, 613 F. Supp. 2d at 280 (dismissing claims as preempted where plaintiff asserted that "it is anticipated that there will be additional violations alleged regarding the Defendants' breaches of federal regulations that correlate with the state duties alleged in the Amended Complaint").

Plaintiffs do not attempt to identify any particular federal law they believe was violated, nor do they offer a theoretical connection between such a violation and Plaintiffs' injuries. In fact, the only specific allegation in their Third Cause of Action involves a Class 2 recall as to the

[16] Remarkably, Plaintiffs even qualify Sara Ali's injuries with this phrase: "Upon information and belief, Plaintiff SARA ALI, suffered and continues to suffer from complications arising from the defective and unsafe LAP-BAND." Amended Complaint ¶ 25.

LAP-BAND® in 2010.[17] Notably, Plaintiffs do not allege the reason for the recall—even though the recall notice itself is publicly available. *See* Class 2 Recall, LAP-BAND® Adjustable Gastric Band System (Nov. 18, 2010) (Exhibit G).[18] As the FDA notice makes clear, the recall was for an efficacy problem—not a safety concern. The FDA's recitation of the "Reason for Recall" was that an issue with respect to the port septum was resulting in patients having "symptoms of reduced satiety and increased appetite." *Id.*[19] There is no suggestion of ***any*** potential injury to patients—much less a serious injury like Plaintiffs allege. Consequently, this circumstance fails to provide any support for a parallel, non-preempted claim that the device caused injury to Mrs. Ali. *See, e.g.*, *Bass v. Stryker Corp.*, ___ F.3d___, No. 11-10076, 2012 WL 266985, at *9 (5th Cir. Jan. 31, 2012) (parallel claim alleged where plaintiff alleged "a concrete injury and a connection between a defect in [the defendant's] manufacture of the [device] and [the] injury"); *Horowitz*, 613 F. Supp. 2d at 283 (FDA recalls and warning letters irrelevant where not shown to be tied to Plaintiffs' injuries or products: "Plaintiff has failed to

[17] Plaintiffs also mention a pre-approval recommendation by the Gastroenterology and Urology Devices Panel in 2000, Amended Complaint ¶¶ 60-61, but that circumstance is entirely irrelevant. As explained above, FDA approved the LAP-BAND® PMA in 2001 and expanded its approved use for the product in 2011. The device could not lawfully be manufactured according to a PMA that was not approved, and Plaintiffs have not asserted—and cannot allege—that the device in this case was manufactured according to unapproved specifications.

[18] Like the other FDA documents in this case, this exhibit is available on FDA's website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=95382 (last visited Feb. 14, 2012).

[19] For context, as explained in the notice, the LAP-BAND® is designed to be inflated through a port just under the skin. *See* Exhibit G ("Product"). The inflation of this port helps the patient limit food consumption by both restricting the opening to the stomach and enhancing the patient's sensation of being full, or satiation, on a smaller quantity of food. *Id.* The doctor, using a special needle, punctures the port and injects saline to inflate the band. The level of saline is used to tighten or loosen the band, as desirable to regulate the amount of food a patient can ingest. If the doctor punctured the port at an angle, it would leave a little hole and allow the saline to leak out gradually. *Id.* ("Reason for Recall"). "Leakage results in deflation of the LAP-BAND to its widest, open position requiring a procedure to replace the port. The patient may have symptoms of reduced satiety and increased appetite." *Id.*

demonstrate that the injuries she sustained resulted from the federal violations spelled out in the [FDA] warning letters."); *see also Covert*, 2009 WL 2424559, at *12 (same).

Plaintiffs' other allegations are entirely conclusory:

- "Upon information and belief," the LAP-BAND "was manufactured in violation of" the FDCA, the MDA, "the terms, conditions, standards and specifications of" the LAP-BAND®'s PMA.

- "Upon information and belief, the LAP-BAND device and its components did not meet and comply with the requirements and functionality as established in the LAP-BAND System Product specifications in the PMA secured by Defendant ALLERGAN from the FDA."

- "Upon information and belief," the LAP-BAND "was adulterated in violation of 21 U.S.C. § 351, in that, among other things, it failed to meet established performance standards and the methods used for its manufacture were not in conformity with federal requirements."

- "Upon information and belief," Allergan "failed to establish, maintain, implement and/or comply with current and effective methods and procedures for the manufacture of the LAP-BAND and to establish and comply with a quality system appropriate to the manufacturing processes employed, in violation of CFR § 820 *et seq.*

- Allergan and its agents "breached their duty to use reasonable care causing Plaintiff [sic] injury."

Amended Complaint ¶¶ 64-67, 70-77, 81. Plaintiffs have essentially accused Allergan of violating just about every conceivable regulation that relates to the manufacturing process, yet Allergan has no idea what Plaintiffs believe it did wrong.

As the Supreme Court has made clear, such conclusions are neither "entitled to the assumption of truth," nor are they plausibly supported by Plaintiffs' factual allegations. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009). Although "legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id.* at 1945, 1950 (The court need not accept as true pleadings that are no more than legal conclusions or the "formulaic recitation of the elements" of a cause of action."); *see also Bell Atlantic Corp. v. Twombly*, 550 U.S. 544,

555 (2007) (party's "[f]actual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)"). Plaintiffs' boilerplate allegations contained in their Third Cause of Action do not meet this standard and therefore provide no support for a parallel claim. *See Bass*, 2012 WL 266985, at *5 ("[T]o plead a parallel claim successfully, a plaintiff's allegations that the manufacturer violated FDA regulations must meet the *Twombly* plausibility standard."); *Desabio*, 2011 WL 4074391, at *5; *Gelber*, 752 F. Supp. 2d at 334; *Horowitz*, 613 F. Supp. 2d at 284.

II. Plaintiffs Have Failed to Allege Fraud With Particularity

In their Amended Complaint, Plaintiffs make a number of conclusory assertions of fraud, many of which are further qualified as based "[u]pon information and belief:"

- ALLERGAN's "advertising was and is deceptive and fails to disclose the relevant warnings, precautions, side effects and contradictions required by the FDA and the serious risk of these adverse health effects to consumers."
- "ALLERGAN made false representations, implied that they had knowledge of the true facts but, in fact, were actually ignorant of the true safety of the product."
- "ALLERGAN, as alleged in paragraphs twenty-seven through thirty-five (27 through 35), suppressed and actively concealed the true facts."

Amended Complaint ¶¶ 37-38, 52. Though they have amended their pleading in response to Allergan's pointed Rule 9(b) challenge, Plaintiffs' fraud claims are no more informative or specific than before. Allergan still does not know what it supposedly misrepresented, when and where those representations were made, whether they were made orally or in writing, by whom or to whom. Instead, Plaintiffs make the situation even worse by adding a "kitchen-sink" allegation that the supposedly fraudulent statements were made in "information distributed to the public, including Plaintiff, the medical and health-care community, and the FDA, by the

defendant ***includ[ing], but [] not limited to*** websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial medical [sic] containing material representations" *Id.* ¶ 45 (emphasis added).

Plaintiffs' fraud allegations amount to no more than "'conclusory allegations or legal conclusions masquerading as factual conclusions [that] will not suffice to prevent a motion to dismiss.'" *S. Christian Leadership Conference v. Supreme Court of Louisiana*, 252 F.3d 781, 786 (5th Cir. 2001) (internal quotations and citation omitted). Rather, under Rule 9(b), "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). To meet the particularity requirement, a plaintiff must "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." *Eternity Global Master Fund Ltd. v. Morgan Guar. Trust Co.*, 375 F.3d 168, 177, 187 (2d Cir. 2004) (citations and internal quotations omitted); *see also In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 366 (E.D.N.Y. 2010). A plaintiff may not base claims of fraud on speculation or conclusory allegations, but, rather, by alleging facts that show that the defendant had the motive and opportunity to commit the fraud, or that constitute strong circumstantial evidence of conscious misbehavior or recklessness. *Eternity Global Master Fund*, 375 F.3d at 186-87.

This heightened pleading standard is more than just a procedural technicality; it provides defendants with fair notice of the plaintiffs' claims, reduces the number of frivolous suits,

protects defendants from harm to their reputation and goodwill, and "discourag[es] fishing expeditions brought in the dim hope of discovering a fraud . . . ." *Wamsley v. LifeNet Transplant Servs. Inc.*, No. 2:10-cv-00990, 2011 U.S. Dist. LEXIS 130760, *10 (S.D. W. Va. Nov. 10, 2011); *see also U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999); *U.S. ex rel. Martinez v. Va. Urology Ctr., P.C.*, No. 3:09-CV-442, 2010 U.S. Dist. LEXIS 77078, at *16 (E.D. Va. July 29, 2010) ("In the absence of sufficiently particularized allegations regarding the time, place, and contents of the representations made to the United States and Commonwealth, and the absence of any clear allegations regarding what was gained through the [allegedly incomplete documents], the Court cannot find that [plaintiff] has established a plausible claim to relief . . . .").

Plaintiffs' allegations fail to attribute identifiable statements to particular statements, speakers, or documents—much less to demonstrate how the alleged statements were misleading or deceptive—and thus fall far short of the mark. *See Fisher v. APP Pharms., L.L.C.*, No. 08-CV-11047 (BSJ), 2011 U.S. Dist. LEXIS 23786, *20-22 (S.D.N.Y. Feb. 28, 2011) (dismissing fraud claims where plaintiff failed to "allege the particular content of the alleged misrepresentations or omissions"). Plaintiffs do not identify a single speaker or publication; instead they simply attribute an assortment of statements to "ALLERGAN." *E.g.*, Amended Complaint ¶¶ 27, 37. Plaintiffs do not assert when and where the supposed misrepresentations were made. Nor does the Complaint indicate that Sara Ali even saw these purportedly false advertisements. The averment that Sara Ali "reasonably relied upon the representations," *id.* ¶¶ 48, 56, is wholly conclusory, as Plaintiffs never indicate what actions she took or did not take as a result of the statements.

The claim that Allergan "suppressed" and "actively concealed" the "true facts," Amended Complaint ¶ 58, is likewise deficient in that it entirely fails to put Allergan on notice of what facts were supposedly concealed and provides no facts "to support a good faith belief" that Allergan defrauded anyone. *See Wamsley*, 2011 U.S. Dist. LEXIS 130760, at *14-18 (averment that defendants "concealed from plaintiff, his doctors, and his hospital" fact that implanted human tissue was infected held insufficient to satisfy Rule 9(b)'s particularity requirement). Plaintiffs have already had the opportunity to amend these claims with a full roadmap of what is required, yet their allegations still fall short. Accordingly, these claims should be dismissed under Federal Rules of Civil Procedure 9(b) and 12(b)(6).

III. Plaintiffs' Warranty Claims Are Preempted

A. The Express Warranty Claim Fails to Survive the MDA's Preemption Provision

Plaintiffs allege that Allergan breached an express warranty that "the LAP-BAND was safe and effective, fit for use by consumers, fit and proper for its intended use, and that it was of merchantable quality . . . ." Amended Complaint ¶ 84. This claim fails for at least three reasons.

First, Plaintiffs' express warranty claim is preempted because it attempts to usurp FDA's exclusive right to determine that the LAP-BAND® is safe and effective and appropriate for certain patients. Although the Supreme Court in *Riegel* did not have occasion to consider an express warranty claim, the District of Minnesota has explained that:

> [E]xpress-warranty claims are preempted for the same reason as . . . implied-warranty claims. Such claims are based on an allegation that the [medical device was] represented as safe . . . . A jury finding in Plaintiffs' favor on such claims . . . would be required to conclude that the [device was] unsafe. As the safety and effectiveness of the [device] are matters solely for the FDA, and because the FDA determined that the [device was] safe and effective when granting PMA, these claims are preempted.

In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147, 1164 (D. Minn. 2009); *see also Bass*, 2012 WL 266985, at *12 ("[E]xpress warranty claims cannot be used to impose requirements greater than that provided by the FDA regulations."); *Gelber*, 788 F. Supp. 2d at 165-66 (S.D.N.Y. 2011) (express warranty claims based on alleged representations as to safety and effectiveness of product were preempted).

Second, to the extent Plaintiffs base their express warranty claim on representations in FDA-approved materials, such as the LAP-BAND® labeling (reprinted in Exhibit F) and the Patient Information Booklet (Exhibit D), their claims are preempted for the reasons discussed above.

Finally, the warranty language in the Patient Information booklet clearly precludes Plaintiffs' claim. That provision (which presumably is the basis for Plaintiffs' express warranty claim), reads as follows:

> Special Notice
>
> The manufacturer of the LAP-BAND Adjustable Gastric Banding System has designed, tested and manufactured it to be reasonably fit for its intended use. However, the LAP-BAND System is not a lifetime product and it may break or fail, in whole or in part, at any time after implantation and notwithstanding the absence of any defect. Causes of partial or complete failure include, without limitation, expected or unexpected bodily reactions to the presence and position of the implanted device rare or atypical medical complications, component failure and normal wear and tear. In addition, the LAP-BAND System may be easily damaged by improper handling or use. Please refer to the Risks, Complications and Adverse Events section in this document for a presentation of the general and specific risks and possible complications associated with the use of the LAP-BAND Adjustable Gastric Banding System

Exhibit D at 69. This language makes perfectly clear that Allergan disclaims any express warranty for failure of the LAP-BAND® device "at any time after implantation." *Id*. For this additional and independent reason, therefore, Plaintiffs' express warranty claim necessarily fails as a matter of law.

B. Plaintiffs' Implied Warranty Claim Is Also Barred

Plaintiffs next allege that Allergan breached an implied warranty that "the LAP-BAND was of merchantable quality and safe and fit for the use it was intended." Amended Complaint ¶ 98. *Riegel* affirmed dismissal of breach of implied warranty claims because the duties underlying those claims impose state law "requirements" that are "different from, or in addition to" requirements imposed by federal law. *See Riegel*, 552 U.S. at 326-30; *see also Horowitz*, 613 F. Supp. 2d at 284 ("For plaintiff to succeed on her claim, a jury would have to find that defendants breached the implied warranty of merchantability by manufacturing a medical device that was unsafe in its federally approved design or manufacture. Such a claim falls squarely within the MDA's preemption provision."). As in *Riegel*, Plaintiffs' claim for breach of implied warranty is preempted.

IV. Plaintiffs' State Law Claims Likewise Fail

A. Virginia's Consumer Protection Laws Can Afford Plaintiffs No Relief

Plaintiffs cannot recover under the Virginia Consumer Protection Act, VA. CODE ANN. § 59.1-196, and their claims in this regard can be dismissed on any and all of the following grounds. First, the claims are preempted because they are based on the same purported misrepresentations contained in Plaintiffs' common law fraud counts.[20] *See Bass*, 2012 WL 266985, at *14 (finding state consumer protection laws preempted by MDA where plaintiffs' purported misrepresentations mirrored failure to warn allegations).

Second, the Consumer Protection Act itself provides that it does not apply to "[a]ny aspect of a consumer transaction which aspect is authorized under laws or regulations of . . . the

[20] In this count, Plaintiffs include statements regarding the effectiveness of the product, *e.g.*, Amended Complaint ¶ 116, which are irrelevant even if credited because Plaintiffs are not seeking damages based on the failure of the product, but rather the personal injuries of Sara Ali.

United States, or the formal advisory opinions of any regulatory body or official of . . . the United States." VA. CODE ANN. § 59.1-199(A). This provision exempts prescription medical devices regulated by FDA, like the LAP-BAND®. *See Hart v. Savage*, No. L-04-1663, 2006 WL 3021110, at *1 (Va. Cir. Ct. Oct. 19, 2006).

Third, the claim contains none of the circumstances and detail required by Rule 9(b) and so is deficient on that basis as well. *See* part II, above.

B. The False Advertising Act Is Likewise Unavailable

Plaintiffs also add claims under the False Advertising Statute, VA. CODE ANN. § 18.2-216, which are similarly preempted. And here too, the claim is far too conclusory to withstand Allergan's Rule 9(b) challenge and should be dismissed.

V. Daniel Ali Has No Claim Against Allergan

Although Daniel Ali originally made a claim for loss of consortium based on the same alleged wrongdoing underlying Sara Ali's claim, Verified Complaint ¶¶ 56-59, he has not brought that claim in the Amended Complaint, and Plaintiffs have admitted that Virginia law does not recognize such a claim. *See Memorandum of Law in Opposition to Defendant's Motion to Dismiss or Alternatively, Motion to Require Repleading of Fraud Claims and Motion to Take Judicial Notice* (Docket #28) ("Opposition") at 4. Nonetheless, he is listed as a "Plaintiff," and the Amended Complaint contains numerous references to "Plaintiffs," which reference appears to assert claims on his behalf. Based on his admission that he has no derivative claim, Daniel Ali should be dismissed as a plaintiff. *Bolen v. Bolen*, 409 F. Supp. 1374, 1375-76 (W.D. Va. 1976) (Virginia Code § 55-36 bars a husband from bringing an action for loss of consortium). Moreover, because the claims by Sara Ali are all preempted and/or otherwise precluded for the reasons set forth above in part I.B. and below in parts II-IV, any derivative claim for loss of

consortium would also fail as a matter of law. *See, e.g.*, *Riegel*, 552 U.S. at 321 n.2 (noting that after granting summary judgment on the plaintiffs' tort claims, the district court "consequently granted summary judgment as well on Donna Riegel's derivative consortium claim."); *see also Gelber*, 788 F. Supp. 2d at 167 (derivative claims under New York law were preempted to the extent that the primary claims were preempted). Consequently, any claim that is asserted by Daniel Ali should be dismissed.

CONCLUSION

For the reasons set forth above, Defendant Allergan, Inc. requests that the Court: (i) grant its renewed Motion to Dismiss; (ii) dismiss Plaintiffs' claims against Allergan for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6); (iii) alternatively, dismiss the conclusory fraud-based claims and require Plaintiffs to replead, if they can, with particularity in accordance with Rule 9(b); (iv) alternatively, dismiss any claims of Daniel Ali against Allergan; and (v) grant Allergan such other and further relief to which it is entitled.

Dated: March 12, 2012

Respectfully submitted,

By: /s/

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CERTIFICATE OF SERVICE

I hereby certify that on the 12th day of March, 2012, I will electronically file the foregoing and its proposed order with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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